## IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	) ) MDL NO. 1203 ) )
THIS DOCUMENT RELATES TO:	
SHEILA BROWN, et al.	) ) ) CIVIL ACTION NO. 99-20593
v.	)
AMERICAN HOME PRODUCTS CORPORATION	) ) ) 2:16 MD 1203

## MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8743

Bartle, J.

December 27, 2011

Before the court is the motion of Linda Smith

("Ms. Smith") for a protective order pursuant to the Diet Drug

Nationwide Class Action Settlement Agreement ("Settlement

Agreement") with Wyeth¹ and the Seventh Amendment to the

Settlement Agreement.

I.

Based on an echocardiogram dated December 13, 2001,
Ms. Smith submitted a claim for Matrix Compensation Benefits

("Matrix Benefits"). As a result of this submission, which

demonstrated at least moderate mitral regurgitation and one of

five complicating factors delineated in the Settlement Agreement,

<sup>1.</sup> Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

Ms. Smith received \$272,707.12 from the Seventh Amendment Fund Administrator. See Settlement Agreement § IV.B.2.c.(2)(b).

Ms. Smith subsequently underwent mitral valve surgery on October 20, 2010. Accordingly, in March, 2011, she submitted a supplemental Green Form to the Trust signed by her attesting physician, Leon J. Frazin. Based on the original echocardiogram dated December 13, 2001, Dr. Frazin attested in Part II of Ms. Smith's Green Form that she underwent mitral valve surgery. Dr. Frazin also noted that Ms. Smith did not suffer from any of the medical conditions, including mitral annular calcification, which would reduce her benefits to Matrix B.<sup>2</sup> See Settlement Agreement § IV.B.2.d.(2).

In connection with Ms. Smith's supplemental claim for Matrix Benefits, the Trust requested records relating to her medical history. These records include but are not limited to the history and physical examination related to her mitral valve surgery and all echocardiograms and reports performed on her in the five years preceding her mitral valve surgery.

II.

Ms. Smith maintains that the Trust is not entitled to the medical records requested. She contends that the Settlement Agreement only permits the Trust to review the echocardiogram on

<sup>2.</sup> If Ms. Smith's supplemental claim for Level III benefits is payable only on Matrix B-1, she will not receive any additional payment because the amount to which she would be entitled for her Matrix B-1, Level III claim is less than the amount she already received for her Matrix A-1, Level II claim. See Settlement Agreement § IV.C.3.

which the claim for Matrix Benefits is based. In addition, she argues that the plain language of § IV.B.2.d.(2)(c) requires that the existence of a reduction factor may only be determined by reference to the "Relevant Echocardiogram," which Ms. Smith defines as the echocardiogram on which her Green Form is based.

Ms. Smith also identified a number of provisions in the Settlement Agreement that she submits have been interpreted similarly, including § IV.B.2.c.(2)(b). Further, she argues that the Settlement Agreement repeatedly refers to "the" echocardiogram or "an" echocardiogram, which, in her view, indicates that the Trust should be permitted to review only a single echocardiogram. Similarly, she asserts that the parties intended, consistent with the language of the Settlement Agreement, the Seventh Amendment, and the Trust's actions in other cases, that each claim be based on a single echocardiogram.

The Trust counters that it is entitled to receive and review the additional medical information. According to the Trust, the echocardiogram tape Ms. Smith submitted with her supplemental Green Form bears a date of January 1, 2002, not December 13, 2001, and does not identify the name of the patient, the physician or healthcare provider who conducted the study, or the location or facility at which the study was performed. The Trust also maintains that its request for additional medical records is permitted because: (1) they are necessary to the Trust fulfilling its responsibility to evaluate claims and confirm that only deserving claimants receive Matrix Benefits;

(2) they are necessary to determine the presence or absence of qualifying and reduction factors, which must be determined with respect to each claim; (3) § VI.C.4.a. of the Settlement Agreement sets forth the minimum requirements to complete a claim for Matrix Benefits; and (4) the Settlement Agreement contemplated that more than one echocardiographic study may be relevant to each claim. Finally, the Trust asserts that Ms. Smith's "single event" theory is unfounded. According to the Trust, her supplemental claim for Matrix Benefits is based on her mitral valve surgery and, as such, the presence or absence of reduction factors at the time of surgery, not at the time of the original claim, is relevant to the determination of benefits.

In her reply, 3 Ms. Smith does not dispute that the Trust is permitted to request "relevant" medical records but maintains that "recent echocardiograms" are not relevant to determine the presence or absence of the reduction factors enumerated in the Settlement Agreement. Relying on the arguments she made in her motion, she submits that the presence or absence of any reduction factors must be determined as of the date she was diagnosed with valvular heart disease.

III.

We conclude that echocardiograms performed in the five years preceding the mitral valve surgery that gave rise to

<sup>3.</sup> Ms. Smith submitted her proposed reply as an exhibit to a motion to file a supplemental brief. We will permit her response.

Ms. Smith's supplemental claim for Matrix Benefits are relevant to her claim. To avoid receiving reduced Matrix Benefits, a claimant must demonstrate, at a minimum, that she did not suffer from a reduction factor at the time she suffered from the conditions supporting her supplemental claim.

The Settlement Agreement provides that:

(2) For Matrix B-1: Diet Drug Recipients who are eligible for Matrix Compensation Benefits and to whom one or more of the following conditions apply, or their Representative Claimants, will receive Matrix Compensation Benefits determined by application of Matrix B-1, provided that such Diet Drug Recipients or Representative Claimants have registered (or are deemed to have registered) for settlement benefits by Date 2:

. . . .

(c) Diet Drug Recipients who ingested Pondimin and/or Redux for sixty-one (61) or more days, who were diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period, with any of the following conditions ....

Settlement Agreement § IV.B.2.d.(2)(c). The plain language of this provision does not contain a temporal limitation on the existence of the conditions that follow. We must apply the Settlement Agreement as written.

Ms. Smith argues that the phrase "with any of the following conditions" must modify "diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between

the commencement of Diet Drug use and the end of the Screening Period." According to Ms. Smith, the condition(s) must be present on the echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period on which she was diagnosed as FDA Positive. In other words, she reads the provision as though it were written: "Diet Drug Recipients who ingested Pondimin and/or Redux for sixty-one (61) or more days, who were diagnosed with any of the following conditions and as FDA Positive by a Qualified Physician by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period." We disagree. The only fair reading of this provision is that the phrase "who were diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period" modifies the Diet Drug Recipients to whom the provision applies, not the timing associated with the diagnosis of a particular reduction factor.

We also reject Ms. Smith's argument that our interpretation of § IV.B.2.c.(2)(b) supports her view. That Section states:

(2) MATRIX LEVEL II is left sided valvular heart disease with complicating factors, and is defined as:

. . .

(b) Moderate MR (20% - 40% RJA/LAA) or Severe MR (>40% RJA/LAA) with one or more of the following ....

Settlement Agreement § IV.B.2.c.(2)(b). We have read this language to mean that "a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement." Pretrial Order ("PTO") No. 8630 at 3 n.5 (Mar. 31, 2011). This Section, unlike § IV.B.2.d.(2)(c), does not contain any commas or qualifying phrases between moderate or severe mitral regurgitation and "with one or more of the following." It is clear that, by the insertion of commas in § IV.B.2.d.(2)(c), the drafters intended the phrase "with any of the following conditions" to modify the phrase "Diet Drug Recipients who ingested Pondimin and/or Redux for sixty-one (61) or more days."

Furthermore, we do not agree with Ms. Smith that the existence of the reduction factors delineated in the Settlement Agreement must be determined at the point when she first qualified for Matrix Benefits. Her claim for Level III benefits did not exist until she underwent mitral valve surgery on October 20, 2010. See Settlement Agreement § IV.B.2.a.(3)(a). Upon the submission of that claim, the Trust was obligated to confirm that there was a reasonable medical basis for Ms. Smith's attesting physician's representations that she did not suffer from any of the reduction factors applicable to her claim.

For the foregoing reasons, the motion of Ms. Smith for a protective order will be denied.